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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/750,466	12/29/2003	Kwang-Chung Lee		9826

7590 07/12/2005  
Lee, Kwang-Chung  
P. O. Box 55-846  
Taipei, 104  
TAIWAN

EXAMINER

GRAZIER, NYEEMAH

ART UNIT	PAPER NUMBER
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1626

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/750,466

Applicant(s)

LEE ET AL.

Examiner

Nyeemah Grazier

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 September 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-5 is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### **I. Action Summary**

Claims 1-5 are currently pending in the instant application. Claim 1 is rejected under 35 U.S.C. 103 and Claim 2 is objected to for minor informalities.

### **II. Priority**

#### ***Priority***

This application claims priority to and benefit of the filing date of foreign application TAIWAN 92103728, filed on February 21, 2003 under 35 U.S.C. 119(a)-(d). Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### **III. Information Disclosure Statement**

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### **IV. Rejection**

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***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

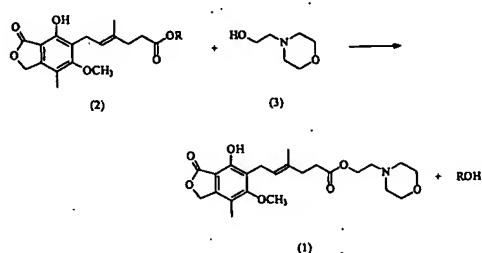
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Knox et al. (U.S. PAT. No. 5,247,083) and Sircar et al. (U.S. PAT. No. 6,709,846) as applied to claim 1 above and in further view of Jerry March, *Advanced Organic Chemistry*, 3d.

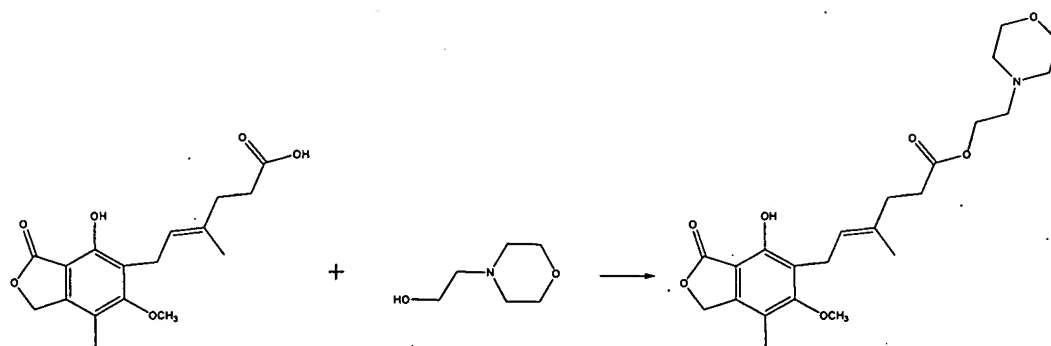
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The instant invention in Claims 1 recites a process of preparing mycophenolate mofetil comprising reacting an alkyl mycophenolate with 2-morpholinoethanol in the presence of a catalyst as described in the scheme below. (See Specification, p. 3).



(1) Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Knox et al. teaches the process of preparing the identical invention, mycophenolate mofetil, by reacting mycophenolic acid with 2-morpholinoethanol in the absence of catalyst to avoid the added cost of a catalyst. However, the patent also teaches the effects of using an acid or base catalyst compared to the process absent a catalyst. (See col. 6, ll. 34-46). Specifically, the reference teaches the process of making mycophenolate mofetil by reacting mycophenolic acid with 2-morpholinoethanol under identical conditions, with acid and base catalysts. Id. The synthetic scheme is described below.



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See also Sircar et al. (WO 00/34503, p.2, ll. 15-22) (teaching the process of preparing the identical product of the invention, mycophenolate mofetil by reacting mycophenolic acid with 2-morpholinoethanol in the presence or absence of an enzyme catalyst).

March teaches general esterification and transesterification reactions of primary alcohols and acids catalyzed by acids and bases. See March, J. *Advanced Organic Chemistry*, 3<sup>rd</sup> Ed., pp. 348-53.

(2) Ascertainment of the Difference Between the Prior Art and the Claims (MPEP §2141.02)

The difference between the prior art of Knox and Sircar and the instantly claimed process is that the Knox and Sircar invention reacts the mycophenolic acid with 2-morpholinoethanol in the presence of a catalyst. The instant application reacts the acid derivative (ester), mycophenolate mofetil, with 2-morpholinoethanol in the presence of a catalyst.

(3)- (4) Finding of Prima Facie Obviousness-The Rational and Motivation (MPEP §2142-2413)

The instant invention and the prior art are related as processes of making mycophenolate mofetil by aliphatic nucleophilic substitution. The instant invention is obvious over the prior references and in view of March because, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make mycophenolate mofetil by transesterification in the presence of a catalyst. Transesterification and esterification reactions are well known to one of ordinary skill in the pertinent art.

The motivation to make claimed compound derives from the expectation that a primary alcohol will react in the presence of an acid or base catalyst with an acid or an acid derivative. In

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re Gyurik, 596 F. 2d 1012, 201 USPQ 552 (CCPA 1979). The teaching of Knox and Sircar in view of March would have motivated one skilled in the art to prepare mycophenolate mofetil by transesterification with the expectation that they would both effectively yield the desired product.

To overcome this rejection, it is suggested that the applicant amend the claim to include the type of catalysts used in the reaction and or reaction conditions essential to the invention, thereby limiting the claim.

V. **Objections**

*Claim Objections*

Claim 2 is objected to because of the following informalities: Claim 2, Part C. contains a typographical error. The claim recites "equeous." Appropriate correction is required.

VI. **Conclusion**

Claim 1 is rejected under 35 U.S.C. 103. Claim 2 is objected to for minor informalities.

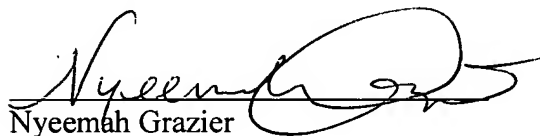
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nyeemah Grazier whose telephone number is (571) 272-8781. The examiner can normally be reached on Monday through Friday from 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane, can be reached on (571) 272 - 0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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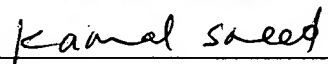
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Very truly yours,

  
Nyeemah Grazier

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